REMARKS/ARGUMENTS

Claims 1-4, 6, 7, 15, 18-21 and 25 are currently pending. Claims 26 - 28 are added.

I. Rejections Under 35 USC §112

The examiner rejected Claim 18 under 35 USC §112, first paragraph. The examiner recognizes that the specification is enabling for promoting lactation in female mammal but argues the specification "does not reasonably provide enablement for promoting reproductive efficiency or success, or fertility." Additionally, the examiner recognizes that the specification is enabling for an edible formulation of ARA but argues that the specification does "has not enabled any other route of administering ARA."

First, Applicants respectfully disagree with the examiner's assertion that the present specification does not enable one of ordinary skill in the art to use the present method for promoting reproductive efficiency, success, or fertility. As examiner has acknowledged, the "relative skill of those in the art is high." One of relative skill in the art would understand the promotion of lactation and/or reproductive efficiency of fertility are not "multiple complex disorders having unrelated manifestations," as asserted by the examiner. Applicant has found that all of these conditions can be improved by the administration of ARA. This is because low ARA levels have been found to adversely effect both lactation and fertility. Applicants' invention, concerning the promotion of reproductive success and fertility, as well as promotion of lactation, results from the establishment of a mouse model of PUFA deficiency (discussed on page 6, line 21 onwards). This mouse model has shown the beneficial effects of ARA before pregnancy, during it, as well as after birth. The various conditions that were adversely affected by PUFA deficiency include lactation, reproductive success, and fertility. This is why, having developed this model, Applicant has enabled one of relative skill in the art regarding the treatment of these conditions because Applicant has found that low levels of ARA in the blood are associated with difficulties or adverse conditions concerning lactation and fertility. Therefore, one of relative skill in the art would be able to use the information provided within Applicants' specification to treat, or at least ameliorate, conditions which contribute to reduced reproductive efficiency, success or fertility.

Additionally, Applicants respectfully disagree that one of relative skill in the art would read the pending claims as encompassing all types of infertility, such as those types which "needs surgical interference" or those types resulting from sterilization.

Given the examiner's acknowledgement that the relative skill of those in the art is high, it is quite clear to those persons skilled in the art would utilize the method of the present invention in those instances that would in fact promote fertility. One of skill in the art would not contemplate the use of a drug or dietary supplement in situations where the condition cannot be treated or could only be treated via surgical procedure.

Second, Applicants respectfully disagree that the present specification has not enabled any other route of administering ARA other than edible formulations. The specification specifically discusses the administration of ARA orally, via pharmaceutical compositions, and edible formulations, including oil formulations. (Specification page 4, line 3 – page 5, line 11) Additionally, ARA, namely arachidonic acid, is a compound which is naturally found in the mammalian body, although usually in a phospholipids form. Therefore, one of relative skill in the art would understand the present specification as being enabling for all known means of administration of a naturally occurring substance, such as oral formulations, edible formulations (including dietary supplements, pills, capsules, animal feed and foodstuffs), and topical formulations, such as ARA oil formulations which could be absorbed through the skin.

II. Rejections Under 35 USC §102

The examiner rejected Claim 15 under 35 USC §102(e) as being anticipated by US 6,200,624. To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. It is insufficient to merely name or describe the desired subject matter, if it cannot be produced without undue experimentation. *See Elan Pharms. Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 68 USPQ2d 1373, 1375-76 (Fed. Cir. 2003). The examiner argued that US '624 "discloses a nutritional supplement comprising 1-15% ARA and 0.1-5% DHA that can be administered to pregnant or lactating human and animal females."

First of all, to support her position that the '624 anticipates that ARA and DHA may be "administered to pregnant or lactating human and animal females," the examiner relies upon one statement within the specification implying that the invention described in the '624 patent "could be used by pregnant and/or lactating females." ('624 Patent, Col. 17, lines 35-37) The '624 patent is directed to the isolation of AA and DHA from egg yolks and the use of the isolated AA and DHA in infant formulas. Unlike Applicants' specification, the '624 patent provides scant details to one of ordinary skill as to why or how DHA and ARA would be administered to pregnant and/or lactating females.

Applicants have amended the method of claim 15 to administration of microbial ARA. Support for this amendment can be found at least at page 3, lines 21-29 of the present application. The '624 patent is directed to the purification of arachidonic acid (AA) and docosahexaenoic (DHA) acid from egg yolks and the advantages to in lieu of the alternative purification methods in the prior art. The '624 patent also teaches their proposed advantages of the use of AA and DHA purified from egg yolks, in lieu of other sources. Egg yolks are an obvious source of ARA because they are known to contain high quantities of ARA and animals and humans naturally eat eggs and egg derived products. This advance in the art, the use of a microbial source of ARA, is not taught or suggested in the '624 patent.

III. Rejections Under 35 USC §103

A. *Rejection of Claims 1-4, 6, 7, 15, 18-21, and 25 over US 6,200,624*

The examiner rejected Claims 1-4, 6, 7, 15, 18-21 and 25 under 35 USC §103(a) as being unpatentable over US 6,200,624. Once again, the examiner argues that US '624 discloses a nutritional supplement comprising 1-15% ARA and 0.1-5% DHA that can be administered to pregnant or lactating human and animal females.

Applicant incorporates by reference the arguments presented in Section II above. Additionally, Applicants argue that the examiner has not established a prima facia case of obviousness. The examiner acknowledges that the '624 patent does not teach "the promotion of lactation." Therefore, it is difficult to image how one of relative skill in the art would take the single statement within '624 patent relied upon by the examiner ("could be used by pregnant and/or lactating females." ('624 Patent, Col. 17, lines 35-37)) to "implicitly" arrive at the present invention. There is nothing in the '624 patent which teaches or suggests the use of ARA and/or DHA for the conditions claimed in claims 15 and/or 18. Prior to the present application, it was not know that the conditions claimed in claims 15 and 18 were linked to low levels of ARA, nor that they could be treated by microbial (rather than egg yolk) source of ARA.

Furthermore, the examiner's arguments that "claimed amounts and ratios, and profile of use are not considered critical" is a complete contradiction to the examiner's current objections to the present application based upon 35 USC §112, paragraph 1. If the examiner argues that the present application is not enabling, with its depth of detail regarding the administration of ARA to pregnant and/or lactating females, her reliance upon this single "implicit" statement within the '624 application

as teaching one of skill in the art the methods of the present invention is pure speculation.

B. *Rejection of Claims 1, 2, 6, 7, 15, and 18 over WO 98/16119*

The examiner rejected Claims 1, 2, 6, 7, 15 and 18 under 35 U.S.C. §103(a) as being unpatentable over WO 98/16119 ('119). The examiner argues that WO '119 teaches "an edible formulation comprising ARA used as foods for pregnant and lactating mothers."

Applicants incorporate the arguments of Sections II and IIIA above. Additionally, Applicants argue that WO '119 suffers from the same deficiencies as outlined above for the '624 patent. The abstract of WO '119 makes a single statement that "[t]he foods ... for pregnant woman and nursing mothers containing [edible fats containing arachidonic acid obtained from *Mortierella*]." There is nothing in the '624 patent which teaches or suggests the use of ARA and/or DHA for the conditions claimed in claims 15 and/or 18. As emphasized above, prior to the present application, it was not know that the conditions claimed in claims 15 and 18 were linked to low levels of ARA. WO '119 makes no mention of promotion of lactation, reproductive success or fertility. As is realized, promotion of reproductive success or fertility will usually happen before pregnancy, rather than during it. While '119 refers to nursing mothers, there is no specific disclosure to the promotion of lactation. Indeed, as ARA is known to naturally exist in breast milk, WO '119 seems to be teaching nothing more than supplementation of such milk by ARA. Such a teaching is entirely different from ARA promoting the lactation process in a female non-human mammal.

Applicants respectfully disagree that WO '119 implies administration to non-human mammal. In fact, the references within WO '119 to "pregnant women" and "nursing mothers" are more likely to be used with respect to humans than to non-humans. Additionally, when viewed in context with the rest of the sentence,

> "[t]he foods include modified milks for premature infants, modified milks for infants, foods for infants, and foods for pregnant women and nursing mothers containing the above-mentioned edible fats"

one cannot find any reference to mammals, other than human. Once again, Applicants argue that the examiner has failed to set forth a prima facia case of obviousness based upon WO '119.

C. *Rejection of Claims 3, 4, 19-21 and 25 over WO '119 in view of Makrides et al.*

The examiner rejected Claims 3, 4, 19-21 and 25 under 35 U.S.C. §103(a) as being unpatentable over WO 98/16119 ('119) in view of Makrides et al. The examiner argues that "Makrides et al. teach a method to increase the DHA in breast milk by dietary supplementation of DHA in amount 0.2 – 1.3 g/day."

Applicant incorporates the arguments made in Sections II, IIIA, and IIIB above. First, Applicant argues that there is no teaching or suggestion to combine WO '119 and Makrides et al. apart from the claims of the present application. The examiner has provided no such reference within WO '119 or Makrides et al. that suggests such a combination.

As recognized by the examiner, Makrides et al. only addresses the use of DHA. Therefore, in view of the deficiencies of WO '119 outlined above, even when combined, Makrides et al. and WO '119 do not teach the methods of the present invention.

In light of the arguments above, Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If the examiner still has concerns regarding allowability of the claims in this application, Applicant respectfully requests a telephonic interview with the examiner to discuss the examiner's concerns.

Respectfully submitted,

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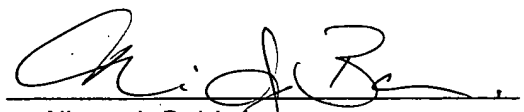
By: 

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